

6. CONCLUSION

At the request of the INVERSION LABORATOIRES, a clinical study was implemented from March to October 2007 in the Clinical Pharmacology Department of University Victor Segalen, Bordeaux 2, on the one hand, and in the CIT company (Bucharest) on the other hand, in order to evaluate the safety, efficiency and acceptability of a food supplement – WP 8-9 – on hair loss of androgenetic origin by men. The same inquiring physician followed the volunteers of this study in these two centres.

Forty-one 28 to 65 years old men (average age: 48.5 years) were included in this study. All suffer from hair loss during the day and during combing, which seems to them abnormally large.

Tolerance:

Tolerance to the studied food supplement is “excellent”. Three volunteers report digestive problems such as nausea or abdominal discomfort, but in any case they appear a few days only and with low intensity. None of the volunteers has raised the issue of termination of the study. They have totally disappeared at the end of study. One volunteer reports an increase in appetite, with little weight gain.

Effectiveness:

The test consists of two distinct periods - four weeks and sixteen weeks - with control every four weeks.

- Period without taking the food supplement (4 weeks)

It comes down to one phase of four weeks during which the subject must perform a daily brushing with a standardized brush delivered during the first control. The hair “fell” during the brushing of this phase are collected in a bag weighed before being distributed to volunteers, and weighed after recovery for knowing the weight of fallen hair for the duration of the phase. A schedule of brushing is also given to each volunteer so he indicates the days during which he performs brushing (ideally daily). The “weight of fallen hair” during this phase can be reduced to the “weight of fallen hair per day”, which corresponds to the “basal fall” in the normal state, without taking the food supplement.

- Period with taking the food supplement (16 weeks)

It consists of four phases of four weeks. Standardized brushing is continued, if possible daily, to recover the fallen hair at each of these phases. The “weight of fallen hair per day” is determined every four weeks and can be compared to the “weight of fallen hair per day” of the initial period, allowing the evaluation of the possible efficiency of the studied food supplement.

So that the hair has the same length during each phase (to compare the weight, the hair length must be the same) each volunteer must get his hair cut within forty eight hours before each test. An explanatory brief for the barber is given to each volunteer at the beginning of the study.

A questionnaire, as well as analogue scales related to “hair” criteria, is completed during each control. Data from these analogue scales, as well as the « weight of fallen hair per day” during the different phases, are subjected to statistical analysis.

Under the conditions of this study:

The amount of “fallen hair” (considered equivalent to the weight) during a standardized brushing during the first phase is significantly greater than the “fallen hair” during each of the following phases. The amount of “fallen hair” decreases steadily and significantly throughout the test. This decrease is highly significant ($p < 0.0001$) when comparing the final phase with the initial phase.

The completed questionnaires at each time of the study clearly demonstrate the positive assessment that the volunteers have on the product. It is clearly demonstrated that the action of this product is considered very favourably about hair loss during the day and during combing, as well as about hair appearance and brightness. It is the same for the action on dandruff, for the volunteers who had dandruff, and for the improvement of oily hair or dry hair.

Finally, the analogue scales confirmed that clear efficiency. For many items, we decided to conclude on EVA analyzed by taking into account only the volunteers who showed impairment of said item under consideration at the beginning of the study.

=> Loss of hair during the day (all volunteers)

Time	Significance	At each time, very significant improvement of hair loss during the day.
φ3/φ1	$p < 0,0001$	
φ4/φ1	$p < 0,0001$	
φ5/φ1	$p < 0,0001$	

=> Loss of hair during combing (all volunteers)

Time	Significance	At each time, very significant improvement of hair loss during combing.
φ3/φ1	$p < 0,0001$	
φ4/φ1	$p < 0,0001$	
φ5/φ1	$p < 0,0001$	

=> Brightness of the hair (volunteers with little shiny hair at the beginning of the study)

Time	Significance	At each time, significant improvement of hair brilliance, very significant at J112.
φ3/φ1	$p = 0,0015$	
φ4/φ1	$p = 0,0002$	
φ5/φ1	$p < 0,0001$	

=> Ease of combing (volunteers with difficulty combing J - 28)

Time	Significance	At each time, significant improvement of the ease of combing.
φ3/φ1	$p = 0,0013$	
φ4/φ1	$p = 0,0032$	
φ5/φ1	$p = 0,0009$	

=> Volume of hair (all volunteers)

Time	Significance	At each time, significant improvement of the volume of hair, very significant from J 84.
φ3/φ1	$p = 0,0003$	
φ4/φ1	$p < 0,0001$	
φ5/φ1	$p < 0,0001$	

=> Dandruff (volunteers having dandruff at the beginning of the study)

Time	Significance	Significant reduction of dandruff from J 84.
φ3/φ1	$p = 0,0684$	
φ4/φ1	$p = 0,0154$	
φ5/φ1	$p = 0,0027$	

=> Oily hair (volunteers with \pm oily hair at the beginning of the study)

Time	Significance	At each time, significant improvement of the oily aspect of the hair.
$\phi 3/\phi 1$	$p = 0,0393$	
$\phi 4/\phi 1$	$p = 0,0042$	
$\phi 5/\phi 1$	$p = 0,0039$	

=> Dry hair (volunteers with \pm dry hair at the beginning of the study)

Time	Significance	At each time, significant improvement of the dry aspect of the hair.
$\phi 3/\phi 1$	$p = 0,0176$	
$\phi 4/\phi 1$	$p = 0,0058$	
$\phi 5/\phi 1$	$p = 0,0014$	

=> Thin hair (volunteers with \pm thin hair at the beginning of the study)

Time	Significance	At the end of the test, significant improvement of the thin aspect of the hair.
$\phi 3/\phi 1$	$p = 0,0176$	
$\phi 4/\phi 1$	$p = 0,0058$	
$\phi 5/\phi 1$	$p = 0,0014$	

Thus, the main items about the hair are steadily and significantly improving throughout the test, all being significantly or very significantly improved when comparing the final phase with the initial phase. This confirms the good efficiency of the studied product - WP 8-9 - on these items.

These favourable judgments are perfectly recovered when analyzing data collected through the questionnaire.

▪ Hair loss during the day is very improved.

- => At the beginning of the study, 67% of volunteers say they lose their hair rather often or very often.
- => At the end of study, none of the volunteers has the same opinion, all consider that the loss has become void or infrequent.
- => At the beginning of the study, 72% of volunteers judge their hair loss rather important or very important.
- => At the end of the study, none of the volunteers has that same opinion, all consider that the loss has become nonexistent or insignificant.

▪ It is the same for the hair loss during combing

- => At the beginning of the study, 92% of volunteers say they lose their hair often or very often.
- => At the end of the study, only one of them (3%) considers that the loss is still quite common.
- => At the beginning of the study, 89% of volunteers judge their hair loss rather important or very important.
- => At the end of the study, none of the volunteers has that same opinion, all consider that the hair loss during combing has become void or insignificant.

- All other items are also improved
 - => At the beginning of the study, many volunteers are reporting poorly brilliant hair, small amount of hair, oily, dry or fine hair, or dandruff.
 - => At the end of the study, all these items are improved.

Finally, volunteers were invited to mark the product under study (on 20) taking into account its main objective, namely the efficiency on hair loss. The average score is 15 / 20.

(Signature and stamp)

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